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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,824	06/25/2001	Eric Perrier	11123.24US01	9749

23552 7590 03/31/2004  
MERCHANT & GOULD PC  
P.O. BOX 2903  
MINNEAPOLIS, MN 55402-0903

EXAMINER

WEBER, JON P

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/888,824

**Applicant(s)**

PERRIER ET AL.

**Examiner**

Jon P Weber, Ph.D.

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 44-64 and 66-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 44-64 and 66-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                                               |                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                                              | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>20040127</u> . | 6) <input type="checkbox"/> Other: _____                                                |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01 December 2003 has been entered. Claims 44-64 and 66-68 are now presented for examination.

***Claim Rejections - 35 USC § 112***

Claims 66-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 66 is confusing. It is not clear how the control is possible. How can the known be present and absent? This step appears to lack antecedent basis. If this concept was incorporated into claim 67, it would make more sense (*vide infra*).

Claim 67 is incomplete. When the activity in the presence of the unknown, U, is less than the activity in the presence of the known, K,  $U < K$ , one does not know if the substance is potentially active in the field of lipolysis, only that it is not as good as the known. That is, there must still be some comparison to the absence of the tested substance as required by claim 44. Thus, one has two reference controls: 1) absence of the test or known compound, and 2) the known compound. In this way one knows if the test compound is 1) an inhibitor at all, and 2) how good an inhibitor it is compared to known compounds.

***Claim Rejections - 35 USC § 103***

Claims 44-64 and 66-68 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US 5,855,917), Wagle et al. (US 6,326,396), Takahashi et al. (US 5,955,072), Takeda et al. (US 5,244,798), Vainio et al. (1982), Cheng et al. (1990), Carroll et al. (1992) and Bensadoun et al. (1974) in view of NEFA-C kit from Wako in view of NEFA-C Kit Instructions and Kikuchi et al. (US 4,301,244).

It is argued that there are eight references, that the references are old, and that the references span many years. It is urged that Takeda et al. do not teach their assay with a cofactor, and that there is no expectation that the NEFA-C kit will work in the presence of LPL, cofactor, BSA and triacylglycerol. It is urged that Vainio et al. use a radioactive method of detecting inhibition.

In response to applicant's argument based upon the age of the references, contentions that the reference patents are old are not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977). The span of dates is not relevant either. No reason is presented why a person of ordinary skill in the art would not look to relevant art regardless of age. The number of references cited is a reflection that LPL is known to be inhibited by a number of compounds. Cook et al. (US 5,855,917), Wagle et al. (US 6,326,396), Takahashi et al. (US 5,955,072), Vainio et al. (1982), Cheng et al. (1990), Carroll et al. (1992) and Bensadoun et al. (1974) were cited for that purpose. Takeda et al. (US 5,244,798), also discloses inhibitors of LPL, as well as the instant assay procedure.

Art Unit: 1651

NEFA-C kit from Wako in view of NEFA-C Kit Instructions and Kikuchi et al. (US 4,301,244) were cited to show the commercially available method for FFA assay is that used by Takeda et al. to assay LPL, establish undisclosed aspects in Takeda et al. such as wavelength choice, and that the assay was not interfered as argued in the previous response. These were cited and relied upon as a rebuttal references. A person of ordinary skill in the art would be greatly motivated to use a commercially available method for assaying FFA because of the well known advantages of ease of practice, detailed instructions from the manufacturer, and reproducibility of the procedure with quality controlled reagents. No further motivation is necessary to select a commercially available assay.

It was previously established that the presence of LPL, BSA and triacylglycerol are not contraindicated by the NEFA-C assay kit which is designed to test for FFAs in blood. This assay was successfully used by Takeda et al. to assay LPL. It is presumed that the claimed "cofactor", if necessary for LPL activity, is inherently present in the assay of Takeda et al., else the enzyme would not exhibit activity. Takeda et al. is the most important reference. Herein the LPL assay in the presence and absence of several compounds that inhibit LPL are determined. By virtue of testing several compounds new claims 66-68 are encompassed.

That applicants desire to interpret the inhibition results as meaning that the compounds are potentially active in the field of lipolysis is not probative of patentability. This is nothing more than mental steps that do not materially change the actual steps taken. This concept is a functional intended use that does not materially change how one assays LPL for inhibition.

Art Unit: 1651

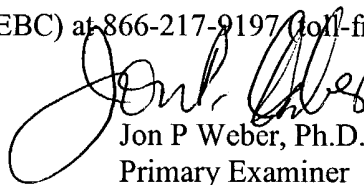
Applicant's arguments filed 01 December 2003 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 103 is adhered to for the reasons of record and the additional reasons above.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 571-272-0925. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jon P Weber, Ph.D.  
Primary Examiner  
Art Unit 1651

JPW  
29 March 2004